PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference A342	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/01377	International filing date *(day/month/year)* 28.03.2003	Priority date *(day/month/year)* 01.04.2002
International Patent Classification (IPC) or both national classification and IPC A61M25/02		
Applicant MOSSANEN-SHAMS, Iden et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
20.10.2003	06.07.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Pascal-Moussellard, Telephone No. +49 30 25901-555

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/01377

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-6 as originally filed

Claims, Numbers

1-12 received on 23.10.2003 with letter of 20.10.2003

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 3,4,7,8,9,11,12

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☒ the claims, or said claims Nos. 3,4,7,8,9,11,12 are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1,2,5,6,10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1,2,5,6,10
Industrial applicability (IA)	Yes:	Claims	1,2,5,6,10
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The amendments filed with the letter dated 20th october 2003 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following: claims 3, 4, 7, 8, 9, 11 and 12.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:
D1: US6086564 A
D2: US-A-2 449 882 (DANIELS AMY J) 21 September 1948 (1948-09-21)
D3: US4257416 A
D4: 5697919 A

The documents D3 and D4 were not cited in the international search report. Copies of the documents are appended hereto.

The application does not meet the requirements of Article 6 PCT, because claim 1 is not clear.
The terms "the provision of a fluid exchange route communicating between a first port and the or each other port of the body" used in claim 1 has no well-recognised meaning and leaves the reader in doubt as to the meaning of the technical feature to which they refer, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.

If claim 1 has to be understood according to the description p.5 l.4-5 as "a body having multiple ports in fluid communication with one another", then, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

The document **D1** is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):
A multiport infusion device to be used as an intravenous administrator of

prescribed fluid, (" The present invention is broadly concerned with an improved patient infusion assembly permitting the safe infusion of multiple fluids into a patient", see D1 col.1 l.6-8 and figure 1) comprising:

a band adapted to be secured to a user's body part near an intravenous therapy location ("the strap 68 supporting infusion body 12 is secured on the patient's wrist or other desired site by adhering the strap 68 to the site; [...] Next, the infusion needle 67 is inserted through the patient's skin adjacent the attachment site", see D1 col.3 l.53-59 and figure 1); and

a multiport body secured to the band (" the body 12 is attached to strap 68 by means of double faced adhesive patches", see D1 col.3 l.47-52 and figure 3) and characterized by the provision of a fluid exchange route communicating between a first port and ("the infusion body 12 is of integral design and includes a total of three essentially identical tubular elements 16, 18, 20 with an interconnecting support web 22 there between" see D1 col.3 l.6-16 and figures 4-9) the or each other port of the body

The subject-matter of claim 1 therefore differs from this known multiport infusion device in that: the three tubular elements are in fluid communication with one another.
The problem to be solved by the present invention may therefore be regarded as how to provide a multiport infusion device in which different fluids can be mixed before being delivered through the delivery port.

The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons.
The feature of having a "mixing manifold passage in open communication with inflow passages" is described in document D3 col.2 l.1-5 and in fig.2 as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal design option to include this feature in the multiport infusion device described in document D1 in order to solve the problem posed.

Document D1, which is considered to represent the most relevant state of the art, discloses (cf. D1) a multiport infusion device from which the subject-matter of claim 2 differs in that the body being in T-piece form.

It is however generally known to the person skilled in the art that the feature T-piece form is an equivalent to the feature Y shape of document D1 and can be

interchanged with that feature where circumstances make it desirable. The Y and T connectors are both well known in the field and can be used alternatively according to the necessity. In this sense the "acute angle" of "the longitudinal axes of the elements 16-20" could be in a T shape. (see for example document D4).

The solution proposed in claim 2 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

2.Dependent claims 5, 6 and 10 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

2.1 The feature of claim 5 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to strap an infusion device on a body.

The features of dependent claim 5 is employed for the same purpose in a similar multiport infusion device, see document D2. It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a multiport infusion device according to document D1, thereby arriving at a multiport infusion device according to claim 5.

2.2 Claim 6 is already known from D1 (see D1 col.3 l.47-52 and Fig. 3).
The subject-matter of claim 6 is therefore not novel (Article 33(2) PCT).

2.3 Claim 10 is already known from D1 (see D1 col.4 l.5-9).
The subject-matter of claim 10 is therefore not novel (Article 33(2) PCT).

AMENDED CLAIMS

Received by the International Bureau on 18 August 2003 (18.08.2003) : original claims 1-13 are replaced by amended claims 1-12.

CLAIMS

1. A multiport infusion device to be used as an intravenous administrator of prescribed fluid, comprising:

a band adapted to be secured to a user's body part near an intravenous therapy location; and

a multiport body secured to the band and characterised by the provision of a fluid exchange route communicating between a first port and the or each other port of the body.

2. A multiport infusion device to be used as an intravenous administrator of prescribed fluid, comprising:

a band adapted to be secured to a user's body part near an intravenous therapy location; and

a multiport body secured to the band and characterised by the multiport body being a T-piece form.

3. The multiport infusion device according to either of Claims 1 or 2 wherein the multiport body is in the form of a block.

4. The multiport infusion device of Claim 3, wherein the multiport body is of substantially constant cross-section.

5. The multiport infusion device of any preceding Claim, wherein the band passes through the multiport body.

6. The multiport infusion device of any preceding Claim, wherein the multiport body is raised from the band allowing air circulation between a tube extending from one of the ports and the intravenous therapy location.

7. The multiport infusion device of any preceding Claim wherein the surface of the multiport body that, in use, will be secured, by the band, against the user's skin, is substantially flat.

8. The multiport infusion device of Claim 7 wherein at least one other major external surface of the body is also substantially flat.

9. The multiport infusion device of Claim 7 wherein each other major external surface of the body is also substantially flat.

10. The multiport infusion device of any preceding Claim, wherein one or more of the ports is provided with a sealing cap.

11. The multiport infusion device of Claim 10, wherein the cap or caps is incorporated into the or each port.

12. The multiport infusion device of any preceding Claim, characterised by the absence of any check valve in any one of the fluid flow passages within the body.